K122956

510(k) Summary according to 807.92(c)
FuseLOX Interbody Fusion System

OCT 25 2012

Date: August 20, 2012

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Trade Name: FuseLOX Lumbar Interbody Fusion System
Product Class: Class II
Classification: 888.3080 Intervertebral Body Fusion Device
Product Codes: MAX
Panel Code: 87

Predicate Device(s): Pivotec Lumbar Interbody Fusion System (K092017), Aleutian IBF System (K113138), and Lumbar I/F Cage (P960025)

Reason for this Submission: This Special 510(k) involves several changes to the previously cleared Pivotec System that allow for:

1. The marketing name for this device will be FuseLOX Lumbar. It is a line extension for the Pivotec Lumbar Interbody Fusion Device (K092017). The Pivotec device is inserted using a pivoting insertion tool for implant delivery, while the FuseLOX Lumbar devices will offer a non-pivoting, threaded insertion tool. The reason for the market name change is to distinguish the two insertion options.
2. Offering two new device configurations, the FuseLOX Lumbar Lordotic and the FuseLOX Lumbar Convex.
3. Added new, non-pivoting inserter design to mate with the FuseLOX Lumbar design.
4. New trial instrument design consistent with the FuseLOX Lumbar design.
5. New tray design to accommodate either Pivotec or FuseLOX Lumbar system's inserter and implant/trial caddy, along with all shared instrumentation.

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Indications for Use/Intended Use: The FuseLOX Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.
The FuseLOX Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Device Description: The FuseLOX Lumbar Interbody Fusion System is an intervertebral body fusion device for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments and promote fusion. The device is made from PEEK-Optima with tantalum or titanium markers. The devices are provided in lordotic and convex configurations with heights ranging from 7-14mm in 1mm increments. Each device has a hollow core to receive bone graft. Placement is achieved with a series of device specific instruments provided.

Performance Testing: Mechanical testing of the subject device consisted of static and dynamic compression, static compression shear, static torsion and subsidence according to ASTM F2077 and ASTM F2267.

Conclusion: The documentation provided demonstrates that the FuseLOX Lumbar Interbody Fusion Device is substantially equivalent to the predicate device listed above. This conclusion is based on the devices' similarities in materials, design, indications for use, clinical application and mechanical function. Captiva Spine concludes that the changes to the system do not introduce any new risks and therefore, the system is Substantially Equivalent to the predicate device, Pivotec Lumbar Interbody Fusion Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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OCT 25 2012

Re: K122956
Trade/Device Name: FuseLOX Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 24, 2012
Received: September 25, 2012

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

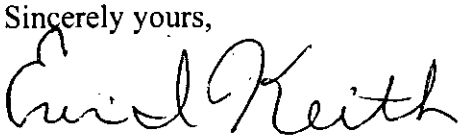
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K122956

The FuseLOX Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The FuseLOX Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122956